STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX
Petitioner

v **File No. 124180-001**

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this _5th___ day of December 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On October 27, 2011, XXXXX, authorized representative for XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. The Commissioner reviewed the material submitted and accepted the request on November 3, 2011.

The Commissioner immediately notified Blue Cross Blue Shield of Michigan (BCBSM) of the external review and requested the information it used in making its adverse determination.

The issue in this external review was first thought to require findings that were medical in nature. The Commissioner, therefore, assigned Petitioner's case to an independent review organization (IRO). The Commissioner directed the IRO to provide the opinion and recommendation of a medical expert. The IRO submitted its report to the Office of Financial and Insurance Regulation (OFIR) on November 17, 2011. However, after thorough review of the information received for review, the Commissioner found that the issue relates to matters of a contractual nature. Therefore, the issue in this case can be resolved by analyzing BCBSM's certificate of coverage, the contract affecting Petitioner's health coverage. It is not necessary to utilize the medical opinion from the independent review organization (IRO). The Commissioner reviews contractual issues under MCL 500.1911(7).

II. FACTUAL BACKGROUND

The Petitioner receives group health care benefits under a *Nongroup Comprehensive Health Care Benefit Certificate* (the certificate). The Petitioner, a 22 year-old man, has been diagnosed with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)[1]. His symptoms have not improved despite treatment under the standard treatment protocol. Petitioner has been recruited to participate in a clinical trial for treatment of his CIDP. Petitioner requested pre-authorization from BCBSM to cover his participation in the trial.

BCBSM denied authorization for coverage as not a benefit under Petitioner's plan. The Petitioner appealed the denial of pre-authorization through BCBSM's internal grievance process. BCBSM held a managerial-level conference on October 14, 2011, and issued a final adverse determination dated October 24, 2011, reaffirming its denial.

III. ISSUE

Did BCBSM properly deny pre-authorization for the Petitioner's participation in the clinical trial?

IV. ANALYSIS

Petitioner's Argument

In a letter dated October 26, 2011, and submitted with Petitioner's request for external review, the physician sponsoring the clinical trial wrote:

> [Petitioner] has severe CIDP that is progressive despite treatment with IVIG, plasmapheresis and high dose steroids. [Petitioner] continues to receive every two weeks IVIG 70 grams with an additional IV Solumedrol 1 gram and Prednisone 20mg daily with little improvement in his symptoms. [Petitioner] has no other health problems and based on clinical literature and medical evidence is likely to benefit from this therapy than from any available therapy.

BCBSM's Argument

In its final adverse determination dated October 24, 2011, BCBSM explained its denial of pre-authorization for the Petitioner's participation in the clinical trial:

> [A]pproved clinical trials include a phase II or [p]hase III trial that have been preapproved by Blue Cross Blue Shield of MI (BCBSM).

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1 Chronic inflammatory demyelinating polyneuropathy (CIDP) is a neurological disorder characterized by progressive weakness and impaired sensory function in the legs and arms. [Retrieved 12/01/2011 from the National Institute of Neurological Disorders and Stroke, National Institutes of Health website. [http://www.ninds.nih.gov/disorders/cidp/cidp.htm]

* * *

> Our Human Organ Transplant Program's Medical Consultant has reviewed the information submitted on your behalf and determined the request from Dr. XXXX is for a pre-approval for a single autologous bone marrow/peripheral stem transplant (Procedure 38241), a Phase I clinical trial. Phase I clinical trials are not a benefit under your plan and the preauthorization is denied.

Commissioner's Review

The certificate excludes coverage for Phase I clinical trials. In Section 6: The Language of Health Care, the Petitioner's certificate states:

> **Approved Clinical Trial:**
>
> A phase II or phase III trial that has been preapproved by BCBSM
>
> **Clinical Trial**
>
> A study conducted on a group of patients to determine the effect of a treatment. For purposes of this certificate clinical trials include:
>
> - Phase II - a study conducted on a number of patients to determine whether the treatment has a positive effect on the disease or condition as compared to the side effects of the treatment.
> - Phase III - a study conducted on a much larger group of patients to compare the results of a new treatment of a condition to the results of conventional treatment. Phase III gives an indication as to whether the new treatment leads to better, worse or no change in outcome.

The Commissioner notes that the trial for which Petitioner seeks approval is a Phase I clinical trial as indicated by its official title, "High Dose Cyclophosphamide & ATG With Hematopoietic Stem Cell Support in Patients With Chronic Inflammatory Demyelinating Polyneuropathy: A Phase I Trial." [2]

Because Petitioner's certificate provides coverage only for phase II and phase III clinical trials, the Commissioner finds that BCBSM's denial of authorization and coverage of Petitioner's participation in the phase I clinical trial is consistent with the terms of the certificate.

2 Retrieved 12/01/2011 from the ClinicalTrials.gov website [http://clinicaltrials.gov/ct2/show/record/NCT00278629?term=nct00278629&rank=1]

V. ORDER

Respondent Blue Cross Blue Shield of Michigan's October 24, 2011, final adverse determination is upheld. BCBSM is not required to authorize coverage for the Petitioner's participation in the phase I clinical trial.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton
Commissioner